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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,119	02/01/2002	Brian Seed	00786/371002	9499
21559	7590	02/12/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/914,119	<b>Applicant(s)</b> SEED ET AL.	
	<b>Examiner</b> T. D. Wessendorf	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/31/03.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,7,9-12,14,15,19,21-23 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,7,9-12,14,15 and 45-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Newly submitted claims 1, 3, 7, 9-12, 14-1 and 45-49 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 1 and 3 are drawn to identifying libraries of polypeptide (vs. non-library of polypeptide as prosecuted in the last Office action). Claims 45-49 are drawn to identifying polypeptides from non-library polypeptide.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 3, 7, 9-12, 14-15 and 45-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Status of Claims***

Claims 1-4, 7, 9-12, 14-15, 19, 21-23, 45-49 are pending in the application.

Claims 1, 3, 7, 9-12, 14-15 and 45-49 are withdrawn from consideration as stated above.

Claims 5-6, 8, 13, 16-18, 20, 24-44 are cancelled.

Claims 2, 4, 19 and 21-23 are under examination.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 19 and 21-23, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

***Response to Arguments***

A). The rejection is no longer applicable with the amendments to claims 1 and 3 and withdrawal from consideration.

B). Applicants argue that the library of step a) is divided into two or more libraries. One would readily recognize that the library may be divided to form two, three, four or more libraries. Applicants further argue that the two or more libraries have "less" complexity than that of the parent library. One of ordinary skill in the art would understand that a library having "less" complexity is one having fewer numbers of different molecules.

In response, applicants are taking the term out of context. It is not clear as to how two is considered less or

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more complex than the preceding library. Furthermore, applicants' argument as it corresponds to the library of step a) makes it more confusing. Is the library of step a) divided prior to step b? There appears to be an essential step missing in the steps. Furthermore, it is not clear as to the fewer numbers of different molecules that would make up a less complex library, as argued. It is not the definition of these relative terms that are at issue. Rather, the context, as applied to the library used in the process steps.

C). The rejection of claims 7-16 no longer applies with the cancellation and withdrawal of these claims.

D). The rejection with respect to claim 7 is inapplicable with the withdrawal of this claim.

E). Claim 13 rejection is moot with the cancellation of the claim.

F). Claim 15 is no longer rejected with the withdrawal from prosecution as being dependent on non-elected claim.

G). Claim 16 has been cancelled.

H). The amendments to the claims and cancellation obviate this rejection.

Claims 2,4, 19, and 21-23, as amended, are rejected as follows:

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1. Claims 2 and 4 are confusing, as there appears to be a lack of nexus with the method steps. Claim 4 is confusing in that step b) recites an "increased" which is contradictory to step d) "decreased"

2. Claims 19 and 21-23 depend on the alternative to the withdrawn claims 1 and 3.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korsmeyer (U.S. 5,834,209) in view of Kamb (WO 98/36097) for reasons of record.

***Response to Arguments***

Applicants admit that Korsmeyer describes a yeast two-hybrid screen in which a library of mammalian proteins fused to a transactivation domain are tested for their ability to bind to the anti-cell death protein Bcl-2 fused to a DNA binding domain. Intermolecular binding between the two fusion proteins leads to

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transcriptional activation of a reporter gene and identification of the protein capable of binding Bcl-2. The Kamb reference is directed to a method of identifying regulatory sequences that modulate gene expression; to that end, Kamb employs GFP as a reporter gene. But argue that there would not have been a reasonable expectation that Korsmeyer's method, used solely in yeast cells, would work in mammalian cells.

Thus, even if one would have had a reasonable expectation that Kamb's reporter gene would function in Korsmeyer's yeast cell assay, as alleged by the Office, it would not follow that one would have a similar expectation that Korsmeyer's method would work in Kamb's mammalian cells, which is necessary to support a rejection of the claims as being obvious. As the presently amended claims now require the use of a mammalian cell, the rejection of these claims as being obvious over Korsmeyer in view of Kamb may be withdrawn.

In response, applicants attention is drawn to col. 5, lines 38-40 and col. 7, lines 20-25 of Korsmeyer which recites that "...it has been unexpectedly discovered that Bad heterodimerizes with bcl-xL and bcl-2 in yeast two-hybrid assays and in vivo in **mammalian cells**....."

Thus, Korsmeyer does not only teach two-hybrid assays but also positively teaches assays in mammalian cell. The combined

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teaching of the prior art therefore renders the claimed invention prima facie obvious.

No claim is allowed.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 1, 3, 7, 9-12, 14-15 and 45-49 drawn to an invention nonelected A complete reply to the

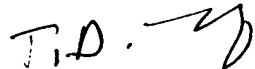


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final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571)272-0811.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw

February 7, 2004